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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 6,384,018	02-2002	Content et al.	
		US- 5,814,617	09-1998	Hoffman et al.	
		US- 5,863,542	01-1999	Paoletti et al.	
		US- 5,753,258	05-1998	Schreier et al.	
		US- 5,755,602	06-16-1998	Xiong et al.	
		US- 5,589,466	12-31-1996	Felgner et al.	
		US- 6,210,663	04-03-2001	Ertl	
		US- 5,679,647	10-1997	Carson et al.	
		US- 6,110,898	08-2000	Malone et al.	
		US- 6,086,901	07-2000	O'Hagan et al.	
		US- 5,462,734	10-1995	Letchworth et al.	
		US- 2003/0021766	01-2003	Vajdy et al.	
		US- 5,843,723	12-01-1998	Dubensky et al.	
		US- 6,015,686	01-18-2000	Dubensky et al.	
		US- 6,015,694	01-18-2000	Dubensky et al.	
		US- 6,110,898	08-2000	Malone et al.	
		US- 6,261,570	07-2001	Parker et al.	
		US- 5,612,201	03-1997	De Plaen et al.	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 00/44410	08-03-2000	Stichting Biomedical Primate Research Centre		
		WO 9747320 A1	12-1997	Schroeder, Ulf		
		WO 02/45741	06-2002	Del Giudice et al.		
		WO 92/11028A	07-09-1992	Ferro		
		WO 94/25601	11-10-1994	Maertens		
		WO 94/24267	10-27-1997	Robinson		

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Sheet 2 of 6

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First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Chapman et al. Nucleic Acid Research. 1991; 19: 3979-3986.	
		Wang et al. Virology. 1995; 211: 102-112.	
		Eldridge et al. Infection and Immunity. 1991; 59 (9): 2978-2986.	
		Pertmer et al. Vaccine. Oct. 1995; 13 (15): 1427-1430.	
		Doe et al. European Journal of Immunology. 1994; 24: 2369-2376.	
		Fields et al. Virology. 3rd ed. Philadelphia: Lippencott Williams and Wilkins; 1995, page 1885.	
		Klein et al. Clinical Therapeutics. 2000; 22 (3): 295-314) on pages 304-305.	
		Marshal: Gene therapy's grpwng pains: Science: Vol. 289: pp. 1050-1055 Aug 1995	
		Mulligan: The basic science of gene therapy: Science: Vol. 260:pp. 926-932 May 1993	
		Wang et al., "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," Vaccine 15:821-825, 1997.	
		HELYAKOV et al., "Induction of a mucosal cytotoxic T-lymphocyte response by intrarectal immunization with a replication-deficient recombinant vaccinia virus expressing human immunodeficiency virus 89.6 envelope protein", J. Virol. (1998), 72 (10): 8264-8272.	
		Rothel et al. "Sequential Nucleic Acid and Recombinant Adenovirus Vaccination Induces Host-Protective Immune Responses Against Taenia Ovis Infection in Sheep." Parasite Immunology. Vol. 19, no. 5, May 1997. p. 221-227.	

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Application Number	09/466,035
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First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁴
		Office ²	Number ³	Kind Code ³ (if known)			
	B1	WO	96/29412	A1	IAF Bio Vac Inc.	09-26-1996	
	B2	WO	99/24578	A2	Chiron S.P.A.	05-20-1999	
	B3	WO	99/36544	A2	Chiron S.P.A.	07-22-1999	
	B4	WO	99/57280	A2	Chiron Corporation	11-11-1999	
	B5	WO	99/61053	A1	Chiron Corporation	12-02-1999	
	B6	WO	00/11140	A1	The Wistar Institute of Anatomy and Biology	03-02-2000	
	B7	WO	00/22430	A2	Chiron Corporation	04-20-2000	
	B8	WO	00/39302	A2	Chiron Corporation	07-06-2000	
	B9	WO	00/50075	A2	Chiron S.P.A.	08-31-2000	
	B10	WO	00/66741	A2	Chiron S.P.A.	11-09-2000	
	B11	WO	00/66791	A1	Chiron Corporation	11-09-2000	
	B12	WO	00/71574	A2	Chiron S.P.A.	11-30-2000	
	B13	WO	00/71725	A2	Chiron S.P.A.	11-30-2000	
	B14	WO	01/04316	A2	Chiron S.P.A.	01-18-2001	
	B15	WO	01/31019	A1	Invitrogen Corporation	05-03-2001	
	B16	WO	01/37863	A2	Chiron S.P.A.	05-31-2001	
	B17	WO	01/38350	A2	Chiron S.P.A.	05-31-2001	
	B18	WO	01/52885	A1	Chiron S.P.A.	07-26-2001	
	B19	WO	01/64920	A2	Chiron S.P.A.	09-07-2001	
	B20	WO	01/64922	A2	Chiron S.P.A.	09-07-2001	
	B21	WO	01/81609	A2	Chiron Corporation	11-01-2001	

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Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	BAGARAZZI et al., "Systemic and mucosal immunity is elicited after both intramuscular and intravaginal delivery of human immunodeficiency virus type 1 DNA plasmid vaccines to pregnant chimpanzees," J. Infect. Dis. 180:1351-1355, 1999	
	C2	BARRE-SINOUSSE et al., "Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS)," Science 220:868-871, 1983	
	C3	BELYAKOV et al., "The importance of local mucosal HIV-specific CD8 cytotoxic T lymphocytes for resistance to mucosal viral transmission in mice and enhancement of resistance by local administration of IL-12," J. Clin. Invest. 102:2072-2081, 1998	
	C4	BRÜHL et al., "An experimental prime-boost regimen leading to HIV type 1-specific mucosal and systemic immunity in BALB/c mice," AIDS Research and Human Retroviruses 14:401-407, 1998	
	C5	CALEY et al., "Humoral, mucosal, and cellular immunity in response to a human immunodeficiency virus type 1 immunogen expressed by a Venezuelan equine encephalitis virus vaccine vector," J. Virology 71:3031-3038, 1997	
	C6	CLAVEL et al., "Isolation of a new human retrovirus from West African patients with AIDS," Science 233:343-346, 1986	
	C7	CLAVEL et al., "Molecular cloning and polymorphism of the human immune deficiency virus type 2," Nature 324:691-695, 1986	
	C8	COONEY et al., "Enhanced immunity to human immunodeficiency virus (HIV) envelope elicited by a combined vaccine regimen consisting of priming with a vaccinia recombinant expressing HIV envelope and boosting with gp160 protein," Proc. Natl. Acad. Sci. USA 90:1882-1886, 1993	
	C9	EO et al., "Prime-boost immunization with DNA vaccine: mucosal route of administration changes the rules," J. Immunology 166:5473-5479, 2001	
	C10	GARDNER et al., "Infection of human dendritic cells by a Sindbis virus replicon vector is determined by a single amino acid substitution in the E2 glycoprotein," J. Virology 74:11849-11857, 2000	
	C11	GRANOFF et al., "Bactericidal monoclonal antibodies that define unique Meningococcal B polysaccharide epitopes that do not cross-react with human polysialic acid," J. Immunology 160:2028-2036, 1998	

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Sheet 5 of 6

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Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C12	GUYADER et al., "Genome organization and transactivation of the human immunodeficiency virus type 2," Nature 326:662-669, 1987	
	C13	JENNINGS et al., "Induction of Meningococcal group B polysaccharide-specific IgG antibodies in mice by using an N-propionylated B polysaccharide-tetanus toxoid conjugate vaccine," J. Immunology 137:1708-1713, 1986	
	C14	JENNINGS et al., "N-Propionylated group B Meningococcal polysaccharide mimics a unique epitope on group B Neisseria Meningitidis," J. Exp. Med. 165:1207-1211, 1987	
	C15	LEE et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with Helicobacter pylori," Vaccine 17:3072-3082, 1999	
	C16	LEVY et al., "Isolation of lymphocytotropic retroviruses from San Francisco patients with AIDS," Science 225:840-842, 1984	
	C17	MOINGEON, "Cancer vaccines," Vaccine 19:1305-1326, 2001	
	C18	MONTAGNIER et al., "A new human T-lymphotropic retrovirus: characterization and possible role in lymphadenopathy and acquired immune deficiency syndromes," in Human T-cell Leukemia/Lymphoma Virus, Gallo, Essex & Gross, eds., pp. 363-379, Cold Spring Harbor Laboratory, 1984	
	C19	POPOVIC et al., "Detection, isolation, and continuous production of cytopathic retroviruses (HTLV-III) from patients with AIDS and pre-AIDS," Science 224:497-500, 1984	
	C20	ROSENBERG, "Progress in human tumour immunology and immunotherapy," Nature 411:380-384, 2001	
	C21	STAATS et al., "Intranasal immunization is superior to vaginal, gastric, or rectal immunization for the induction of systemic and mucosal anti-HIV antibody responses," AIDS Research and Human Retroviruses 13:945-952, 1997	
	C22	VILMER et al., "Isolation of new lymphotropic retrovirus from two siblings with hHaemophilia B, one with AIDS," The Lancet 1:753-757, 1984	

Examiner Signature		Date Considered	
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NON PATENT LITERATURE DOCUMENTS

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		CAIRNS et al., "New Viral Vectors for HIV Vaccine Delivery," <i>Aids Research and Human Retroviruses</i> (Mary Ann Liebert, ed., US) (1998), 14 (17): 1501-1508.	
		HARIHARAN et al., "DNA Immunization against Herpes Simplex Virus: Enhanced Efficacy Using a Sindbis Virus-Based Vector," <i>J. Virol.</i> (1998), 72(2): 950-958.	
		KANO et al., "Induction of SIV-specific immune responses by using recombinant sendai viral vector," 7 th Conference on Retroviruses and Opportunistic Infections, [Online] 30 January 2000 - 2 February 2000, retrieval from the Internet: <URL: http://www.retroconference.org/2000/abstracts/807.htm >, abstract 807 [retrieved on 2004-01-28].	
		POLO et al., "Stable alphavirus packaging cell lines for Sindbis virus- and Semliki Forest virus-derived vectors," <i>PNAS USA</i> (1999), 96: 4598-4603.	
		TSUJI et al., "Recombinant Sindbis Viruses Expressing a Cytotoxic T-Lymphocyte Epitope of a Malaria Parasite or of Influenza Virus Elicit Protection Against the Corresponding Pathogen in Mice," <i>J. Virol.</i> (1998), 72(8): 6907-10.	
		VAJDY et al., "Human Immunodeficiency Virus Type 1 Gag-Specific Vaginal Immunity and Protection After Local Immunizations with Sindbis Virus-Based Replicon Particles," <i>J. of Infect. Diseases</i> (2001), 184: 1613-1616.	
		Harcourt, G.C. "HIV-1 Variation Diminishes CD4 T Lymphocyte Recognition" <i>J. Exp. Med.</i> (1998) 188, 10, 1785-1793	
		VILLACRES et al., "Maintenance of CD8+ T-Cell Memory Following Infection with Recombinant Sindbis and Vaccinia Viruses," <i>Virology</i> (2000), 270: 54-64.	
		Hu et al. "Immunization with HIV-1 GP160 enhances HIV-specific immune responses elicited by vaccinia-HIV recombinant virus" 6 th International Conference on AIDS, 1990, San Francisco, page 205.	
		Bohm et al. "DNA vector constructs that prime hepatitis B surface antigen-specific cytotoxic T lymphocyte and antibody responses in mice after intramuscular injection" <i>Journal of Immunological Methods</i> , vol. 193, 14, June 1996. 29-40	
		Li et al. "Priming with recombinant influenza virus followed by administration of recombinant vaccinia virus induces CD8+ t-cell-mediated protective immunity against malaria." <i>PNAS</i> , vol. 90, 1993, 5214-5218.	
		Sallberg et al. "Characterization of humoral and CD4+ cellular responses after genetic immunization with retroviral vectors expressing different forms of the hepatitis B virus core and E antigens." <i>Journal of Virology</i> . Vol. 71, no. 7, July 1997. 5295-5303.	

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